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Paper 8
Entered: April 26, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.,
Petitioner,

v.

CONFORMIS, INC.,
Patent Owner.

Case IPR2017-00115
Patent 9,216,025 B2

Before BEVERLY M. BUNTING, JAMES A. WORTH, and AMANDA F. WIEKER, *Administrative Patent Judges.*

WORTH, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

On October 20, 2016, Smith & Nephew, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–20 (the "challenged claims") of U.S. Patent No. 9,216,025 B2 (Ex. 1001, "the '025 patent"). On January 31, 2017, Patent Owner, ConforMIS, Inc. ("Patent Owner"), filed a Preliminary Response (Paper 7, "Prelim. Resp.") thereto.

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition filed under [35 U.S.C. §] 311 and any response filed under [35 U.S.C. §] 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.108. For the reasons set forth below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that claims 1–20 are unpatentable. Accordingly, we institute an *inter partes* review of claims 1–20 based on the grounds identified in the Order section of this decision.

A. Related Matter

The parties identify the following district court proceeding as a related matter: *ConforMIS, Inc. v. Smith & Nephew, Inc.*, No. 1:16-cv-10420-IT (D. Mass. Feb. 29, 2016). Pet. 1; Paper 5, 2. The parties also identify the following Board proceeding as related: IPR2016-01874. Pet. 1; Paper 5, 2.

B. The '025 Patent (Ex. 1001)

The '025 patent is titled "Joint Arthroplasty Devices and Surgical Tools" and relates to compositions and tools for repairing articular surfaces, where implants or prostheses are customized for the patient to achieve optimal fit, and tools are customized for the patient to increase the speed,

accuracy, and simplicity of a surgical procedure, i.e., a partial or total arthroplasty. *See* Ex. 1001, at [54], [57], 1:29–34, 5:20–25; *see also id.* at 7:53–8:29 (certain embodiments). The '025 patent describes a need in the art "for compositions for joint repair, including methods and compositions that facilitate the integration between the cartilage replacement system and the surrounding cartilage" and for "tools that increase the accuracy of cuts made to the bone in a joint in preparation for surgical implantation of, for example, an artificial joint." *Id.* at 5:9–15.

In one embodiment, the '025 patent discloses an articular prosthesis comprising an external surface located in the load bearing area of an articular surface, wherein the dimensions of said external surface achieve a near anatomic fit with the adjacent, underlying, or opposing cartilage. *Id*. at 6:52–57. The '025 patent discloses that the shape of an implant such as a prosthesis can be based on an analysis of an electronic image (e.g., MRI, CT, digital tomosynthesis, or optical coherence tomography). *Id*. at 39:45–55; *see also id.* at 8:50–9:30.

In another embodiment, a mold for a tool can be created with pre-operative CT or spiral CT imaging of a joint to determine the thickness of articular cartilage. *See id.* at 50:39–54, Fig. 23. Figure 24B of the '025 patent is depicted below:

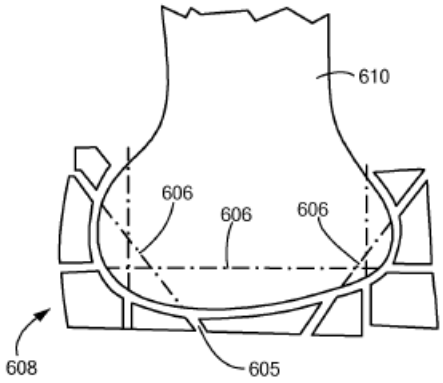


FIG. 24B

Figure 24B illustrates, in cross-section, an example of surgical tool 600/608 containing apertures 605 through which a surgical drill or saw can fit and which guide the drill or saw to make cuts or holes in bone 610. *See id.* at 11:57–59, 51:51–65. Dotted lines represent where cuts 606 corresponding to the apertures will be made in bone. *Id.* at 11:59–61.

The ’025 patent discloses that “[t]he biomechanical axis can be defined as the axis going from the center of the femoral head, between the condylar surfaces and through the ankle joint.” *Id.* at 15:38–40. The ’025 patent discloses that axis information is determined or estimated with a CT scan or X-ray and is used to create the implants. *Id*. at 16:40–47, 16:60–62, 17:13–15.

C. Illustrative Claim

Claims 1 and 15 are independent. Independent claim 1, reproduced below, is illustrative of the subject matter:

> 1. A surgical system including an articular repair system and a patient-specific surgical tool for use in surgically repairing a joint of a patient, wherein the patient-specific surgical tool comprises:

> a block having a patient-specific surface and first and second guides;
>
> the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged cartilage surface of the joint of the patient;
>
> the first and second guides having predetermined positions and orientations relative to the patient-specific surface and being oriented to provide two predetermined drilling or cutting paths that are aligned relative to a biomechanical or anatomical axis of the joint and through a portion of the joint of the patient when the patient-specific surface is placed against the corresponding diseased or damaged cartilage surface of the joint of the patient.

Ex. 1001, 61:16–34.

D. The Alleged Grounds of Unpatentability

Relying on the Declaration of Dr. Jay D. Mabrey, M.D. (Ex. 1002), Petitioner sets forth its contentions that claims 1–20 are unpatentable based on the grounds list in the following table. Pet. 24–90. As a preliminary matter, we observe that the Petitioner sets forth the ground of unpatentability based on Radermacher, Alexander, and Woolson as one grouping of references but pleads this ground of unpatentability in the alternative based on the use of references in subgroupings or individually, e.g., based on Radermacher alone or Radermacher in combination with the knowledge of a person of ordinary skill in the art. See Pet. 24–79. Taking the references in the alternative as presented would, as a practical matter, expand what is asserted as one ground into three (or more) separate grounds of unpatentability. The function of the Board is not to comb through Petitioner's arguments in order to decipher the strongest argument or to

determine the strongest combination of references to challenge the claims. As such, we exercise our discretion and consider all of the references in combination as one ground of unpatentability. *See* 35 U.S.C. § 314(a); 35 C.F.R. § 42.108; *see generally LG Elecs., Inc. v. Rosetta-Wireless Corp.*, Case IPR2016-01516 (PTAB Apr. 3, 2017) (Paper 25) (denying rehearing).

Reference(s)	Basis	Claims challenged
Radermacher[1], Alexander[2], and Woolson[3]	§ 103	1, 2, 5–16, 19, and 20
Radermacher, Alexander, Woolson, and Biscup[4]	§ 103	2–4[5] and 16–18[6]

[1] Radermacher, WO 93/25157, pub. Dec. 23, 1993 (Ex. 1003).

[2] Alexander, WO 00/35346, pub. June 22, 2000 (Ex. 1004).

[3] Woolson, US 4,841,975, iss. June 27, 1989 (Ex. 1031).

[4] Biscup, US 2004/0117015 A1, pub. June 17, 2004 (Ex. 1035).

[5] In the previous ground, Petitioner includes a footnote as part of the discussion of claim 2, which states: "To the extent that the Board finds that this limitation is not disclosed or obvious in view Radermacher or Woolson, it would have been obvious to a POSITA in view of Biscup, as discussed in connection with Claim 3." Pet. 45 n.6. In other words, Petitioner pleads in the alternative and asserts claim 2 both as part of the ground based on Radermacher, Alexander, and Woolson, and as part of the ground based on Radermacher, Alexander, Woolson, and Biscup. We consider claim 2 as part of this latter ground.

[6] Petitioner argues for the unpatentability of claim 16 based on the same reasoning as claim 2. Pet. 53, 78. We accord claim 16 the same treatment as claim 2, *i.e.*, as part of the ground based on Radermacher, Alexander, Woolson, and Biscup. See note 5, *supra*.

Reference(s)	Basis	Claims challenged
Radermacher, Fell[7], and Woolson	§ 103	1, 2, 5–16, 19, and 20
Radermacher, Fell, Woolson, and Biscup	§ 103	2–4 and 16–18[8]

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs. v. Lee, LLC*, 136 S. Ct. 2131, 2142–46 (2016). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

[7] Fell, WO 00/59411, pub. Oct. 12, 2000 (Ex. 1005).

[8] Petitioner asserts the grounds based on Fell, relying on similar contentions and asserted reasoning as for the grounds based on Alexander, *i.e.*, with Fell substituted for Alexander in the latter asserted grounds. *See* Pet. 85. Accordingly, we include claims 2 and 16 in the ground based on Radermacher, Fell, Woolson, and Biscup for the same reasons as for the grounds based on Radermacher, Alexander, Woolson, and Biscup. See notes 5–6, *supra*.

We construe claim terms only as relevant to the parties' contentions and only to the extent necessary to resolve the issues in dispute. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). Petitioner states that claim construction is not required, but proposes a construction for the term "articular surface," as recited in claim 15. Pet. 21. Patent Owner does not propose construction of any terms. *See generally* Prelim. Resp. 1–3. For clarity, we construe the term "articular surface." We also provide a construction for an additional term that relates to claims 7 and 8, i.e., "cutting slot."

Petitioner proposes, and Patent Owner does not dispute, that the term "articular surface" refers to "the bone surface and/or cartilage surface of an articulating portion of a joint." Pet. 21. Our review of the specification reveals that "[t]he articular surface can comprise cartilage *and/or* subchondral bone." Ex. 1001, 6:22–24 (emphasis added). As such, the Specification recognizes that subchondral bone may underlie cartilage but that subchondral bone may also be exposed, i.e., in a diseased joint where the cartilage has worn away. *See, e.g.*, *id.* at 1:51–54. For purposes of this Decision, we construe the term "articular surface" as "the surface of an articulating bone that includes cartilage and/or exposed subchondral bone." The Declaration of Dr. Mabrey is consistent with this understanding of the term "articular surface." *See* Ex. 1002 ¶ 36.

We also provide a construction for the term "cutting slot" (or "cutting slots"), as it variously appears in claims 7 and 8. We note that Dr. Mabrey observes that it was known in the art that a cutting guide in a surgical tool could take the form of a cutting slot or a cutting surface. *See* Ex. 1002 ¶ 42. Although a cutting surface may serve the same purpose as a cutting slot (*see*

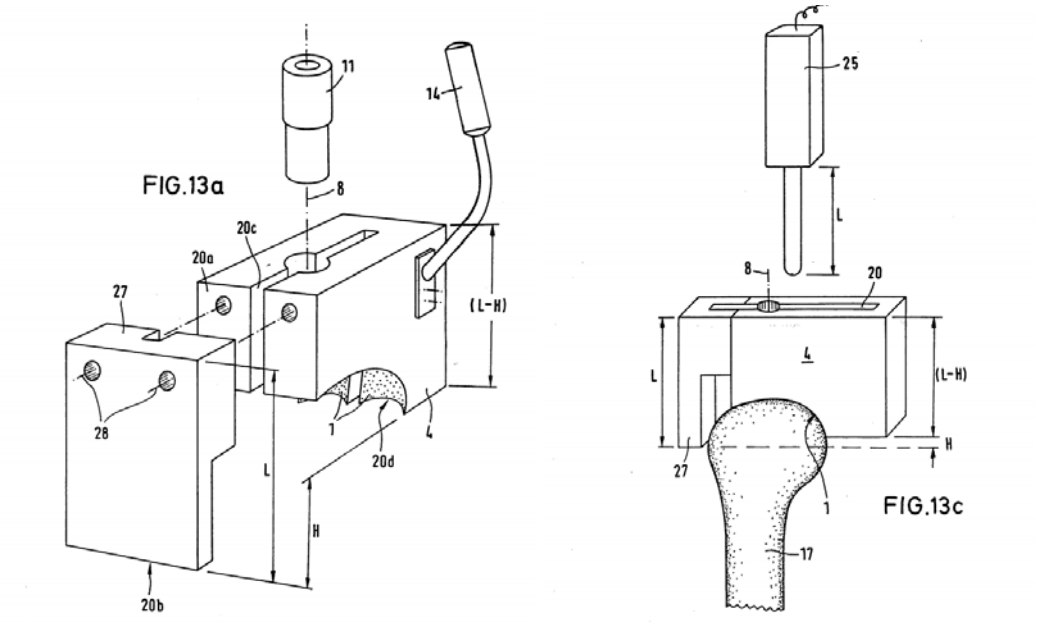
id.), we construe the term, as it would be understood by a person of ordinary skill, such that a cutting slot is "an elongated cutting guide internal to a surgical tool," as opposed to the surface of a surgical tool. *See* Ex. 1001, 45:31–34 (separately referring to slots, apertures, and holes), Fig. 25B & 25D (slots 2328, aperture 2330), 52:56–67 (explaining Figs. 25B&D).

B. Obviousness over Radermacher (Ex. 1003), Alexander (Ex. 1004), and Woolson (Ex. 1031)

Petitioner contends that claims 1, 2, 5–16, 19, and 20 are unpatentable as obvious over Radermacher, Alexander, and Woolson. Pet. 24–79. Patent Owner disagrees. Prelim. Resp. 1–26.

1. Radermacher

Radermacher is titled "Template for Treatment Tools and Method for the Treatment of Osseous Structures" and relates to certain improvements in the planning and performance of orthopedic surgery. *See* Ex. 1003, 1, 9. Radermacher describes a method in which parts of the surface of an arbitrary osseous structure, which are to be operated upon, are copied as a negative image using computer or nuclear-spin imaging so that an individual template can be set intra-operatively onto the osseous structure with mating attachment. *Id.* at 10:5–13. Radermacher discloses that the template can provide a guide corresponding to the limiting edge of a cut through the osseous structure (e.g., a vertebra) and can guarantee sufficient accuracy by exact positioning and guidance of the cutting tool. *Id.* at 16:5–19. Figures 13a and 13c of Radermacher are depicted below:



Figures 13a and 13c schematically show an individual template 4 for the preparation of the seat for a knee-joint head prosthesis. *Id.* at 30:5–8.

2. Overview of Alexander

Alexander is titled "Assessing the Condition of a Joint and Preventing Damage" and relates to using joint assessment in aiding in prevention of damage to the joint or treatment of diseased cartilage in the joint. Ex. 1004, 1:15–17. Alexander discloses a method of obtaining an image of cartilage, (preferably a magnetic resonance image), converting the image to a three-dimensional degeneration pattern, and evaluating the degree of degeneration in a volume of interest of the cartilage. *Id.* at 2:25–27. Alexander further discloses calculating the thickness or regional volume of the region thought to contain degenerated cartilage, both at an initial time and a later time, to determine a loss in thickness. *Id.* at 3:3–8. Alexander also describes creating a "3D" thickness map. *Id.* at 3:8–9.

3. Overview of Woolson

Woolson is titled "Preoperative Planning of Bone Cuts and Joint Replacement Using Radiant Energy Scan Imaging" and relates to a method of preoperative planning to determine the position of a bone-cut-defining guide relative to the bone to be cut. Ex. 1031, 1:12–14. Woolson discloses steps of (1) preoperative determination of the angle between the anatomical and mechanical axes of the femur from radiographs; (2) localization of the center of the femoral head by external markers after operative radiographs are taken and correct estimation of the center of the distal femur for the external alignment system of femoral alignment; and (3) visual estimation of the centers of the proximal tibia and of the ankle joint in both the coronal and sagittal planes for correct tibial component alignment. *Id.* at 1:65–2:10.

Woolson further discloses surgical guides, as shown in Figures 7A and 7B, which are reproduced below:

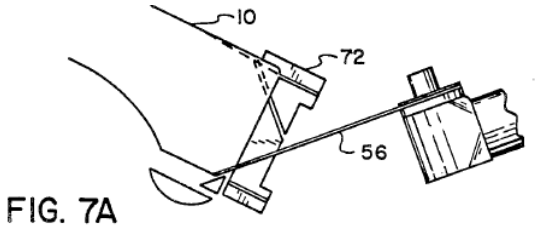


FIG. 7A

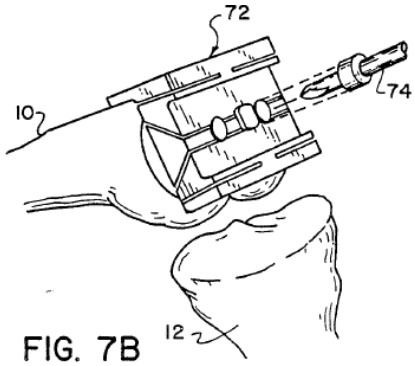


FIG. 7B

Figures 7A and 7B present a lateral view and a perspective view of a cutting guide for making final femoral cuts. *Id.* at 3:39–40.

4. Analysis

In its Petition, Petitioner sets forth its contentions as to how the limitations of claims 1, 2, 5–16, 19, and 20 are disclosed in, or obvious over,

the combination of Radermacher, Alexander, and Woolson. Pet. 24–79. See notes 5–6, *supra*.

a. Independent claim 1

As to the preamble, Petitioner states that Radermacher discloses surgical systems that include both a "'knee-joint head prosthesis' (articular repair system) and an 'individual template' (patient-specific surgical tool) for use in knee joint surgery." Pet. 24–25, 54 (citing Ex. 1003, 10, 18–19, 25–26, 30, Figs. 10a–e, 13a–d). On the current record, we determine that Petitioner has made a sufficient showing that Radermacher discloses an articular repair system with a patient-specific surgical tool. In particular, Radermacher indicates that a prosthesis will be implanted after the knee-joint is prepared by cutting (and drilling) the femur with the assistance of the template of Figures 13a-13c. *See* Ex. 1003, 19, 30.

As to the limitations "a block having a patient-specific surface and first and second guides" and "the patient-specific surface having at least a portion that is substantially a negative of a corresponding portion of a diseased or damaged cartilage surface of the joint of the patient," as recited by claim 1, Petitioner relies on the disclosure in Radermacher of an individual template copied as a negative image from pre-operative computer imaging. Pet. 26–31, 54–56 (citing Ex. 1003, 10, 12, 13, 18, 19, 21–22, 25–26, 30, Figs. 13a–d, 18, 19). For example, Radermacher states that

> the central functional element is a so-called individual template by which parts of the surface of an arbitrary osseous structure which is to be treated and is intraoperatively accessible to the surgeon, are copied as a negative image without undercut and in a mechanically rigid manner, so that the individual template can be set onto the osseous structure in a clearly defined position and with mating engagement.

> According to the inventive method, there is used a split-field device (e.g. a computer or a nuclear spin tomograph) by which split images are produced of the layers extending through the body of the living organism and containing the osseous structure, and from these split images, data regarding the three-dimensional shape of the osseous structure and the surface thereof are obtained. In the preoperative planning phase, these data are used as a basis for defining, within the coordinate system fixedly positioned relative to the osseous structure, a rigid individual template which, completely or by segments (but at least by three intraoperatively clearly identifiable abutting points), copies the surface of the osseous structure in such a manner that the individual template can be intraoperatively set onto these – then freely exposed – contract faces or points in exclusively one clearly defined position in form-closed manner.

Ex. 1003, 10–11 (*cited and excerpted at* Pet. 26). Petitioner additionally relies on the disclosure in Radermacher of a negative mold of the natural surface of the osseous structure, as follows:

> By 3D reconstruction of a tomographically imaged object, particularly of the osseous structures of a living human, and by visualizing this reconstruction on an output medium, particularly a computer monitor, and particularly by using a computer system or a computer-based display and construction system, there is generated a three-dimensional negative mold of parts of the individual natural (i.e. not pre-treated) surface of the osseous structure intraoperatively accessed by the surgeon.

Ex. 1003, 12 (*cited and excerpted at* Pet. 27).

Petitioner also relies, in combination with Radermacher, on the knowledge of a person of ordinary skill in the art, in asserting that it would have been obvious to match the template of Radermacher with the contact faces of the cartilage surface, i.e., to the extent that the articular surface is covered with cartilage. *See* Pet. 29–31 (citing Ex. 1002 ¶¶ 43, 93–95).

According to Petitioner, the person of ordinary skill in the art "would have understood that when Radermacher discloses that the template is generated via a three-dimensional negative mold of parts of the individual natural, not pre-treated surface and 'set onto the bone' ([Ex. 1003,] 30), this means that the template is set onto the un-treated bone, i.e., on top of any remaining cartilage (and any exposed subchondral bone)." Pet. 29 (citing Ex. 1002 ¶ 90).

With respect to the knowledge of a person of ordinary skill, Petitioner asserts that a person of ordinary skill would have been motivated to match the contact faces to cartilage rather than underlying subchondral bone because (a) the cartilage surface and the subchondral bone surface are the only two surfaces to which Radermacher's custom template could be matched; (b) the choice between the two is merely a design choice and reflects a choice from a finite number of identified, predictable solutions with a reasonable expectation of success; (c) matching the cartilage surface would simplify the surgery, if it does not have to be removed in order for the template to precisely fit; (d) Radermacher teaches that the contact faces match the "natural (i.e. not pre-treated) surface"; and (e) a person of ordinary skill would understand that matching the cartilage would result in a template that has "one spatially uniquely defined position," reduces surgical time, and increases accuracy, as Radermacher teaches. Pet. 29–31 (citing Ex. 1002 ¶ 94; Ex. 1003, Abstract, 9; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 402–403 (2007)). On this basis, Petitioner reasons that it would have been obvious to a person of ordinary skill in the art to match the "contact faces" of Radermacher's template to the size, shape, and/or curvature of the

patient's articular cartilage as derived from the MRI data. Pet. 30 (citing Ex. 1002 ¶¶ 93–95).

With respect to Alexander, Petitioner asserts that it would have been obvious to combine Alexander's teaching of imaging and mapping articular cartilage therewith such that the contact faces of Radermacher's template are substantially a negative of the patient's cartilage surface. Pet. 31–33 (citing Ex. 1004, 2:5–6). Petitioner argues that it would have been obvious to a person of ordinary skill in the art to combine Alexander's disclosure that imaging techniques could be used to determine the dimensions of joint cartilage, with Radermacher's imaging techniques, in order to achieve the goal of simplifying surgery and because it would have been consistent with Radermacher's goals for creating a custom template. *See id*. at 34. Petitioner also asserts, *inter alia,* that this would have been a combination of known elements to achieve a predictable result with a reasonable expectation of success. *Id*.

On the current record, we determine that Petitioner has made a sufficient showing that the combination of Radermacher and Alexander, taken in light of the knowledge of a person of ordinary skill, disclose the limitation of a patient-specific surface that is based on a negative image of the articular surface. In particular, Radermacher discloses a template that is a negative mold of parts of the individual natural (i.e., not pre-treated) surface based on radiographic imaging. Ex. 1003, 10–12. Further, Alexander discloses radiographic imaging to determine the size and shape of the articular cartilage. Ex. 1004, 2:25–27. We further determine that Petitioner has made a sufficient showing that it would have been obvious to a person of ordinary skill to incorporate Alexander's imaging of cartilage in

the manufacture of Radermacher's surgical tool, *inter alia*, because Radermacher discloses a negative mold of the articular joint. Ex. 1003, 12. Additionally, we determine that Petitioner has made a sufficient showing that Radermacher discloses first and second guides in a cutting tool. In particular, Radermacher discloses axis 8 for drilling and groove 20c for cutting. Ex. 1003, 13, Fig. 13c.

As to the limitation "the first and second guides having predetermined positions and orientations relative to the patient-specific surface," as recited in independent claim 1, Petitioner relies on drill guide 8 and cutting guides 13a–d in Figure 13a of Radermacher. Pet. 35–36. On the current record, we determine that Petitioner has made a sufficient showing that Radermacher discloses first and second guides with predetermined orientations relative to the surface. In particular, Radermacher discloses that "the cutting, boring, milling and other treatment steps . . . are three-dimensionally charted in said coordinate system fixed relative to the osseous structure" "in the preoperative surgical planning phase." Ex. 1003, 11.

As to the further limitation of the first and second guides:

> being oriented to provide two predetermined drilling or cutting paths that are aligned relative to a biomechanical or anatomical axis of the joint and through a portion of the joint of the patient when the patient-specific surface is placed against the corresponding diseased or damaged cartilage surface of the joint of the patient

as recited by claim 1, Petitioner acknowledges that Radermacher does not refer to a biomechanical or anatomical axis. Pet. 37. However, Petitioner suggests that Radermacher's tool is necessarily aligned relative to such an axis and that it was widely known to do so. *Id.* at 37–38. Nevertheless, Petitioner relies in combination on the teaching in Woolson that it is

"necessary" that the cutting paths be perpendicular to the mechanical axis. Pet. 39 (citing Ex. 1031, 4:9–19). Petitioner further contends that it would have been obvious to a person of ordinary skill in the art to combine the teachings of Woolson regarding cutting perpendicular to a mechanical axis with Radermacher's surgical tool because of Woolson's teaching that it would have been "necessary" to do so. *See id.* at 39–43. On the current record, we determine that Petitioner has made a sufficient showing that Woolson discloses cutting perpendicular to the biomechanical axis. Ex. 1031, 4:9–19. We further determine that Petitioner has made a sufficient showing that it would have been obvious to a person of ordinary skill to combine the teachings of Woolson with those of Radermacher (and Alexander) because Woolson discloses that it would have been "necessary" to cut perpendicular to the biomechanical axis to achieve better results. *Id.*; *see also* Pet. 41–43.

We note that Patent Owner does not, in the Preliminary Response, dispute Petitioner's individual factual contentions. Rather, the Preliminary Response primarily argues that the grounds asserted in the Petition are horizontally and vertically redundant, i.e., within and across grounds. *See* Prelim. Resp. 6–22. Further, Patent Owner argues that the Petition has provided insufficient evidence for instituting based on Radermacher alone, or Radermacher in combination with the knowledge of a person of ordinary skill in the art. *See id.* at 10–16. Based on our determination not to institute based on Radermacher alone or Radermacher in combination with the knowledge of a person of ordinary skill as discussed in Section I D, many of Patent Owner's arguments are moot at this time.

Patent Owner also argues that Petitioner has impermissibly broken independent claim 1 into individual elements for purpose of analysis. Prelim. Resp. 22–24. Although we are mindful that obviousness for any given claim is determined in light of the claim as a whole, we do not find, at this stage of the proceeding, that Petitioner has impermissibly focused on individual elements of independent claim 1 to the exclusion of analyzing the claim as a whole.

For the foregoing reasons, we determine that Petitioner has demonstrated a reasonable likelihood that the combination of Radermacher, Alexander, and Woolson renders obvious the repair system and tool of claim 1.

b. Claims 5–15, 19, and 20

Petitioner contends that claims 5–15, 19, and 20 are disclosed by the combination of Radermacher, Alexander, and Woolson.

Claim 5 depends from claim 1 and further recites "wherein the joint is one of a hip, knee, ankle, shoulder, elbow and wrist joint." Ex. 1001, 61:45–46. Petitioner relies Radermacher, *inter alia*, for surgery on a knee. Pet. 45, 63 (citing, e.g., Ex. 1003, 30). On this record, we determine that Petitioner has made a sufficient showing. For example, Radermacher discloses a template for preparation of a knee joint. Ex. 1003, 30, Figs. 13a–13d.

Claim 6 depends from claim 1 and further recites "wherein the first and second guides are holes configured to accommodate and direct a surgical drill." Ex. 1001, 61:47–49. Petitioner relies alternatively on at least Figures 6B and 9 of Radermacher and on Figure 7B of Woolson. Pet. 45, 64–66 (citing, e.g., Ex. 1003, 13, 25–26, Figs. 6b, 9, 10a-d, 13c; Ex. 1031, 6:58–63, Fig. 7B; Ex. 1002 ¶¶ 128–137). On this record, we determine that

Petitioner has made a sufficient showing that Woolson contains two drilling guides. For example, Woolson discloses two holes which serve as guides for drill 74 as shown in the template of Figure 7B. *See* Ex. 1031, 3:39–40, 6:57–62.

Petitioner argues that it would have been obvious to a person of ordinary skill to combine the multiple drilling guides of Woolson with the template of Radermacher in order to use an implant containing two pegs, as taught in Woolson, as opposed to one peg as taught in Radermacher. Pet. 49–50 (citing Ex. 1002 ¶ 136). We determine at this stage of the proceeding that Petitioner has made a sufficient showing that it would have been obvious to combine the teachings of Woolson and Radermacher, as asserted. Specifically, Dr. Mabrey avers that it was commonplace to use an implant with two pegs and that a person of ordinary skill would have used two drilling holes to accommodate these implants. We note that this reasoning for the combination of Woolson and Radermacher would apply equally to claims 7–15, 19, and 20, *infra*.

Claim 7 depends from claim 1 and further recites "wherein the first and second guides are cutting slots." Ex. 1001, 61:50–51. Petitioner relies alternatively on Figures 13a and 13c of Radermacher and on Figure 7A of Woolson. Pet. 50–51, 67 (citing Ex. 1003, 13, 30, Figs. 13a, 13c; Ex. 1031, 6:63–64, Fig. 7A; Ex. 1002 ¶¶ 145–147). On this record, we determine that Petitioner has made a sufficient showing. For example, Woolson discloses elongated cutting guides interior to surgical tool 72, which are used for anterior, posterior, and chamfer cuts, made by saw 56, in the template of Figures 7A and 7B. *See* Ex. 1031, 3:39–40, 6:54–64.

Claim 8 depends from claim 1 and further recites "wherein the first guide is a hole configured to accommodate and direct a surgical drill and the second guide is a cutting slot." Ex. 1001, 61:52–54. Petitioner relies alternatively on Figures 13a–c of Radermacher and on Figure 7B of Woolson. Pet. 52, 68 (citing Ex. 1003, 30, Figs. 13a–c; Ex. 1031, 6:58–63, Fig. 7B; Ex. 1002 ¶ 148). On this record, we determine that Petitioner has made a sufficient showing. Radermacher discloses both drilling hole 8 and cutting slot 20c. Ex. 1003, 30; *see also* Ex. 1031, Fig. 7B.

Claim 9 depends from claim 1 and further recites "wherein the first and second guides are aligned along distinct cutting planes when the patient-specific surface is fit to the corresponding portion of the diseased or damaged cartilage surface of the joint of the patient." Ex. 1001, 62:1–5. Petitioner relies alternatively on Figures 13a–c of Radermacher and on Figure 7A of Woolson. Pet. 52, 69–70 (citing Ex. 1003, 30, Figs. 13a–c; Ex. 1031, Fig. 7A; Ex. 1002 ¶ 149). On the current record, we determine that Petitioner has made a sufficient showing, for similar reasons as for claims 7 and 8.

Claim 10 depends from claim 1 and further recites "wherein the first and second guides are co-planar." Ex. 1001, 62:6–7. Petitioner relies alternatively on Figures 13a–c of Radermacher and on Figure 7B of Woolson. Pet. 52, 71, 72 (citing Ex. 1003, 30, Figs. 13a–c; Ex. 1031, 6:58–63, Fig. 7B; Ex. 1002 ¶ 150). Petitioner contends that the drilling holes of Woolson are co-planar. On the current record, we determine that Petitioner has made a sufficient showing. Woolson's template sits along the femur, in a plane, after the femur has been cut. *See* Ex. 1031, 3:39–40, 6:30–64. Petitioner has made a sufficient showing, on this record, that it would have

been obvious to incorporate the template of Woolson into the template of Radermacher which is a negative image of a joint, if a surgeon intends to make the repair of Woolson, i.e., with pegs in holes in the femur. *See* Pet. 49–50.

Claims 11–14 relate to similar features of a template with cutting guides in different planes. Claim 11 depends from claim 1 and further recites "wherein the first and second guides are not co-planar." Ex. 1001, 62:8–9. Claim 12 depends from claim 1 and further recites "wherein the first and second guides are aligned along distinct cutting planes when the patient-specific surface is fit to the corresponding portion of the diseased or damaged cartilage surface of the joint." *Id*. at 62:10–13. Claim 13 depends from claim 12 and further recites "wherein the patient-specific surgical tool includes a third guide." *Id*. at 62:14–15. Claim 14 depends from claim 13 and further recites "wherein the third guide is a slot aligned along a second plane to provide a second cutting path that is aligned through a portion of the joint when the patient-specific surface is placed against the corresponding portion of the diseased or damaged cartilage surface of the joint." *Id*. at 62:15–21. Petitioner relies variously on Figures 13a–c of Radermacher and on Figures 7A and 7B of Woolson. Pet. 52, 72–76 (citing Ex. 1003, 30, Figs. 13a–c; Ex. 1031, 6:58–63, Figs. 7A, 7B; Ex. 1002 ¶¶ 150–151, 153–154). On the current record, we determine that Petitioner has made a sufficient showing, for the same reasons as discussed *supra* for claims 7 and 8.

Claim 15 is independent and contains similar recitations as independent claim 1 and dependent claim 6. Ex. 1001, 62:22–38. We determine, at this stage of the proceeding, that Petitioner has provided a

sufficient showing for claim 15, for the same reasons as discussed *supra* for dependent claim 6, and for independent claim 1 (discussed in Section II.B.4.a.). *See* Pet. 52, 76–78.

Claim 19 depends from claim 15 and contains similar recitations as dependent claim 5. Ex. 1001, 62:49–50. We determine, at this stage of the proceeding, that Petitioner has provided a sufficient showing for claim 19, for the same reasons as for dependent claim 5. *See* Pet. 53, 78.

Claim 20 depends from claim 15 and further recites "wherein the block containing the patient-specific surface and the drilling holes are comprised of a single component." Ex. 1001, 62:51–53. Petitioner relies alternatively on Figures 1a, 6, 10, and 13a of Radermacher and on Figure 7B of Woolson. Pet. 53, 79 (citing Ex. 1003, 13, Figs. 1a, 6, 10, 13a; Ex. 1031, 3:39–40, Fig. 7B). On the current record, we determine that Petitioner has made a sufficient showing. In particular, Woolson discloses a single cutting guide in Figures 7A and 7B, which has two holes for drilling guides. *See* Ex. 1031, 3:39–40.

For these reasons, we determine that Petitioner has established a reasonable likelihood of prevailing on its contentions that claims 5–15, 19, and 20 are obvious over the combination of Radermacher, Alexander, and Woolson.

C. Obviousness over Radermacher, Alexander, Woolson, and Biscup (Ex. 1035)

Petitioner contends that claims 2–4 and 16–18 are unpatentable as obvious over the combination of Radermacher, Alexander, Woolson, and

Biscup. Pet. 43–45 n.6, 62–63, 80–85. Patent Owner disagrees. Prelim. Resp. 22.[9]

1. Overview of Biscup

Biscup is titled "Molded Surgical Implant and Method" and relates to a customized prosthetic implant for use in fully or partially replacing bone and/or tissue in a human or animal. Ex. 1035, at [54], [57], ¶ 2. Biscup states that bone replacements typically do not provide full function or range of movement that is provided by a healthy, properly formed bone and that there remained a need for a prosthetic implant that closely matches a bone and/or tissue to be replaced. *Id.* ¶ 17. Biscup discloses a method of selecting a standard prosthetic implant having a close shape and size to that which is required and then further shaping the implant with molding material based on X-ray or MRI data to customize it to the patient. *See id.* ¶¶ 88–89.

2. Analysis

a. Claims 2 and 16

Claim 2 depends from claim 1 and further recites "wherein the articular repair system includes one or more implant components selected for the patient from preexisting systems." Ex. 1001, 61:35–37. Petitioner relies on Radermacher, the knowledge of a person of ordinary skill, Woolson, and Biscup for the "preexisting systems" limitation. Pet. 43–45. Petitioner states that (a) Radermacher teaches that the customized templates can be used in conjunction with "standard tool guides"; (b) Radermacher

[9] Patent Owner's arguments with respect to this asserted ground are similar to those made with respect to the ground based on Radermacher, Alexander, and Woolson (addressed in Section II.B.4.a., *supra*).

does not indicate that the implant is anything other than a conventional, off-the-shelf implant from a preexisting system; and (c) a person of ordinary skill would have understood Radermacher's implant to be a preexisting, standard implant that is compatible with the preexisting, standard tool guide. *Id*. at 44 (citing Ex. 1003, 2, 11; Ex. 1002 ¶¶ 138–139). Petitioner additionally relies on the description in Woolson that once the appropriate cuts have been made to the patient's bone, the "remainder of the surgical procedure is carried out as usual," which Petitioner asserts includes the use of actual prostheses from a preexisting system. *Id*. at 44–45 (citing Ex. 1031, 7:57–62; Ex. 1002 ¶ 141). Petitioner further relies on Biscup for the disclosure of selecting a "generic implant" for a patient. Pet. 45 n.6 (citing Ex. 1035 ¶ 88, Fig. 2; Ex. 1002 ¶ 142).

On the current record, we determine that Petitioner has made a sufficient showing that Biscup discloses an implant selected from a preexisting system. In particular, Biscup discloses selecting a standard prosthetic implant for further modification. Ex. 1035 ¶¶ 88–89. Petitioner argues that it would have been obvious to a person of ordinary skill to use the system of Biscup to make the template as used in Radermacher, *inter alia*, because Biscup discloses that its system can be used to quickly, accurately, and cost effectively customize an implant to size for a particular patient. *See id*. ¶ 17. We determine, on this record, that Petitioner has made a sufficient showing that it would have been obvious to incorporate the teachings of Biscup regarding manufacture of a customized implant with Radermacher's system of articular repair. Therefore, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on its

contention that the combination of Radermacher, Alexander, Woolson, and Biscup renders obvious claim 2.

Claim 16 depends from claim 15 and contains the same additional recitation as claim 2. *Compare* Ex. 1001, 62:39–41, *with id.* at 61:35–37. On the current record, we determine that Petitioner has demonstrated a reasonable likelihood that the combination of Radermacher, Alexander, Woolson, and Biscup renders obvious claim 16, for the same reasons as for claim 2, and for claim 15 (discussed *supra* in Section II.B.4.b.).

b. Claims 3, 4, 17, and 18

Claim 3 depends from claim 2 and further recites "wherein the selected one or more implant components are further shaped based on electronic image data of the joint of the patient." Ex. 1001, 61:38–40. Petitioner relies on the disclosure of a prosthesis in Biscup, in combination with the prior art relied on in the previous asserted ground based on Radermacher, Alexander, and Woolson. Pet. 80. On the current record, we determine that Petitioner has made a sufficient showing. In particular, Biscup discloses modifying an implant with molding material based on information obtained by "various electronic devices," such as X-ray or MRI data. Ex. 1035 ¶¶ 88–89.

Claim 4 depends from claim 1 and further recites "wherein the articular repair system includes one or more implant components designed for the patient using electronic image data of the joint of the patient." Ex. 1001, 61:41–44. On the current record, we determine that Petitioner has made a sufficient showing for the same reasons as for claim 3, and for claim 2 (discussed *supra* in Section II.C.2.a.).

Claim 17 depends from claim 16 and contains a further recitation that is identical to that of claim 3. *Compare* Ex. 1001, 62:42–44, *with id.* at 61:38–40. On the current record, we determine that Petitioner has made a sufficient showing for the same reasons as for claim 2 (discussed in Section II.C.2.a., *supra*), and for claim 15 (discussed in Section II.B.4.b., *supra*).

Claim 18 depends from claim 17 and contains a further recitation that is identical to that of claim 4. *Compare* Ex. 1001, 62:45–48, *with id.* at 61:41–44. On the current record, we determine that Petitioner has made a sufficient showing for the same reasons as for claim 3, and for claim 15 (discussed in Section II.B.4.b., *supra*).

For these reasons, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on its contention that claims 2–4 and 16–18 are rendered obvious over the combination of Radermacher, Alexander, Woolson, and Biscup.

D. Obviousness over Radermacher, Fell (Ex. 1005), and Woolson

Petitioner contends that claims 1, 2, 5–16, 19, and 20 are unpatentable as obvious over Radermacher, Fell, and Woolson. Pet. 85–89. Patent Owner disagrees. Prelim. Resp. 19–22.[10]

1. Overview of Fell

Fell is titled "Surgically Implantable Knee Prosthesis" and relates to prosthetic devices and, more particularly, to self-centering knee joint prostheses which may be surgically implanted between the femoral condyle

[10] Patent Owner's arguments with respect to this asserted ground are similar to those made with respect to the ground based on Radermacher, Alexander, and Woolson, addressed above.

and tibial plateau of the knee. Ex. 1005, 1:4–5. Fell discloses a hard, self-centering meniscal device suitable for implantation into the knee compartment defined by the space between the femoral condyle and the respective tibial plateau. *Id.* at 4:6–9. Fell discloses that the natural meniscus may be maintained in position or may be wholly or partially removed. *Id.* at 5:13–15. Fell further discloses that the meniscal device allows for the provision of non-contacting or recessed areas to encourage articular cartilage regeneration. *Id.* at 8:28–30. Fell describes that the shapes of the affected femoral condyle and tibial plateau are ascertained using X-ray or MRI imaging to determine the correct geometry of the meniscal device for a given patient. *Id.* at 14:5–28. Figure 7 of Fell is depicted below:

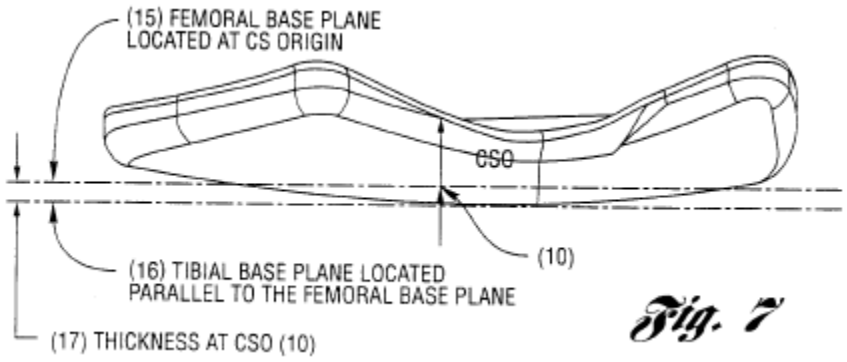


Figure 7 of Fell illustrates a device contour and its relationship with the femoral and tibial base planes. *Id.* at 5:1–2.

2. Analysis

Claims 1, 5–15, 19, and 20

Petitioner relies on Fell for similar teachings as Alexander, i.e., with respect to imaging of articular cartilage. *See* Pet. 85–89. With respect to independent claim 1, Petitioner relies on Radermacher, as above, for the teachings of a surgical tool and relies on Fell in combination therewith for

teaching of matching the surgical tool to the cartilage of the articular surface. *Id.* In particular, Petitioner relies on the teaching in Fell of determining the size, shape, and curvature of the cartilage surface using MRI data. *See* Pet. 85–86 (citing Ex. 1005, 15, 22). Petitioner further relies on Woolson for the teaching of cutting perpendicular to the mechanical axis of the femur. *See id.* 60–61, 88. On this record, Petitioner demonstrates sufficiently that Fell, like Alexander, discloses imaging the shape of the articular cartilage. For example, Fell discloses constructing a contour plot of the femoral and tibial mating surfaces and the size of the meniscal cavity, using MRI, in order to produce a custom-tailored meniscal implant. *See* Ex. 1005, 15:12–16.

Petitioner reasons that a person of ordinary skill in the art would have adopted the techniques of Fell to create a cutting guide, as taught by Radermacher, *inter alia*, in order to match the patient's joint surface. Pet. 85–88 (citing, e.g., Ex. 1002 ¶¶ 172, 175–179). On this record, we determine that Petitioner's proffered rationale and evidence is sufficient to support the proposed combination of the teachings of Fell regarding the measuring of cartilage in preparation for deployment of an orthopedic surgery device with the cutting guide of Radermacher. In particular, Fell discloses a method for producing "custom tailored" devices that specifically takes into account the shape of the articular cartilage. *See* Ex. 1005, 15:12–21. Therefore, we determine that Petitioner has established a reasonable likelihood of prevailing on its contention that the combination of Radermacher, Fell, and Woolson renders obvious independent claim 1.

For similar reasons as for independent claim 1, we determine that Petitioner has made a sufficient showing with respect to claims 5–15, 19, and 20. Petitioner is relying on Fell instead of Alexander for the contact

faces of the device of Radermacher and is otherwise relying on the same evidence from Radermacher and Woolson in the ground based on Radermacher, Fell, and Woolson, as in the ground discussed above based on Radermacher, Alexander, and Woolson. *See* Pet. 85. Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on its contention that the combination of Radermacher, Fell, and Woolson renders obvious claims 5–15, 19, and 20, for the same reasons as for the ground based on the combination of Radermacher, Alexander, and Woolson.

E. Obviousness over Radermacher, Fell, Woolson, and Biscup

Petitioner contends that claims 2–4 and 16–18 are unpatentable as obvious over the combination of Radermacher, Fell, Woolson, and Biscup. See *supra*, notes 5–6. Patent Owner disagrees. Prelim. Resp. 22.[11]

For similar reasons as for independent claims 1 and 15, we determine that Petitioner has made a sufficient showing with respect to claims 2–4 and 16–18. Petitioner is relying on Fell instead of Alexander for the contact faces of the device of Radermacher, as recited in independent claims 1 and 15 (*see* Pet. 85), and is otherwise relying on the same evidence from Radermacher and Biscup in the ground based on Radermacher, Fell, Woolson, and Biscup, as in the ground discussed above based on Radermacher, Alexander, Woolson, and Biscup. *See* Pet. 89–91. Petitioner additionally asserts that Fell discloses customized implants in certain embodiments and pre-existing implants in other embodiments. Pet. 90

[11] Patent Owner's arguments with respect to this asserted ground are similar to those made with respect to the ground based on Radermacher, Alexander, and Woolson, addressed above.

(citing Ex. 1005, 14–15). Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on its contention that the combination of Radermacher, Fell, Woolson, and Biscup renders obvious claims 2–4 and 16–18, for the same reasons as for the ground based on the combination of Radermacher, Alexander, Woolson, and Biscup.

III. CONCLUSION

We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 1–20 of the '025 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted on the following grounds:

Claims 1, 5–15, 19, and 20 as obvious over Radermacher, Alexander, and Woolson;

Claims 2–4 and 16–18 as obvious over Radermacher, Alexander, Woolson, and Biscup;

Claims 1, 5–15, 19, and 20 as obvious over Radermacher, Fell, and Woolson;

Claims 2–4 and 16–18 as obvious over Radermacher, Fell, Woolson, and Biscup;

FURTHER ORDERED that no other proposed grounds of unpatentability are authorized; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

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